UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

DOUGLAS J. HORN and CINDY HARP-HORN,

Plaintiff,

-vs-

MEDICAL MARIJUANA, INC.,
DIXIE HOLDINGS, LLC a/k/a DIXIE ELIXERS
RED DICE HOLDINGS, LLC, and
DIXIE BOTANICALS,

Defendants,

AFFIDAVIT OF KENNETH D. GRAHAM, Ph.D.

Case No. 15-cv-701 FPG/MJR

I, Kenneth D. Graham, Ph.D., declares the following, pursuant to 28 USC §1746, under penalty of perjury:

1. I am a Forensic Toxicologist, pharmacologist and pharmacist with over 25 years of experience in the field. I was retained on behalf of the Plaintiffs to evaluate the evidence and testimony involving the tetrahydrocannabinol (THC) content of the Dixie X Elixir Tincture product taken by Plaintiff. I am fully familiar with the facts and circumstances set forth in this affidavit.

2. I make and submit this affidavit in response to plaintiff's Motion in Limine to preclude certain proposed trial exhibits of plaintiff.

3. When called for testimony at the trial of this matter, among other relevant aspects, I will testify as follows;

4. The complaint is based on plaintiff Douglas Horn's alleged use of Dixie X CBD Dew Drops 500mg Tincture on successive days in early October 2012.

5. As a commercial truck driver, the plaintiff was subjected to random urine drug screens as required under U.S. Department of Transportation protocols.

6. On or about October 9, 2012, a urine sample was collected from the plaintiff for the purpose of performing a random drug screen.

7. On October 11, 2012, the plaintiff 's employer informed him that his urine drug screen produced a positive finding for the presence of tetrahydrocannabinol metabolite (THC metabolite or carboxy THC) and he was subsequently terminated from his employment.

8. Following the loss of his job, the plaintiff purchased a bottle of Dixie X 100mg CBD Dew Drop Tincture that had a lower CBD content than a 500mg product but was presumably otherwise formulated in the same manner as the 500mg tincture product he consumed.

9. The plaintiff submitted the 100mg CBD tincture product he purchased to EMSL Analytical, Inc, a nationally recognized provider of testing services to professionals and the general public. The company is an ISO 17025 certified chemical testing facility like those engaged by defendants for the testing of their products. According to an affidavit prepared by EMSL, the laboratory maintains an extensive list of accreditations from leading organizations including state and federal regulating bodies.

10. EMSL measured a concentration of 170µg/mL (170ppm) THC in the 100mg CBD tincture submitted by the plaintiff. Since the fundamental issue was whether a CBD tincture similar to the one Mr. Horn consumed contained THC as a potential source of the drug that yielded a positive finding in the plaintiff's urine sample, assessment of the CBD content was irrelevant and was not measured. CBD and THC are distinct, independent components of the product and measurement of one does not affect, negate or undermine the measurement of the other. The analysis of the product supplied to EMSL by Mr. Horn was not intended to confirm the label

claim of the product CBD content. The THC content was measured as an absolute concentration in the product and not as a relative concentration to CBD.

11. The product was not returned to the Plaintiff by EMSL since it contained THC, a Schedule I controlled substance, and could not be shipped to an individual who was not registered with the DEA.

12. Although the Dixie X 100mg Dew Drop Tincture had a different CBD content from the product the plaintiff consumed, it had a measurable THC content and was presumably produced in an equivalent manner and in a similar timeframe as the product the plaintiff consumed.

13. The defendants have not produced any batch record, release testing or certificates of analysis information of the exemplar product that would show the product did not contain THC. Contrary to defendant's claim that their products are tested multiple times during the manufacturing process using both traditional ISO 17025 chemical testing facilities and cannabinoid testing facilities, the lack of documentation indicates either that the product Mr. Horn took was not tested before it was sold or their manufacturing, documentation and record keeping processes are deficient.

14. The defendant's expert, Dr. Cindy Orser, was not provided with any batch record, release testing or certificates of analysis information of the exemplar product for her review. Instead, defendant's provided Dr. Orser with certificates of analysis produced by CannLabs for several surrogate 500mg CBD products, manufactured around October 2012, upon which she based her analysis and conclusions. Dr. Orser acknowledged that the surrogate 500mg CBD products contained measurable THC content. Since the defendants provided test records to

their expert that were intended to serve as representative product proxies in the absence of actual manufacturing records for the product used by plaintiff, the test results also showing measurable THC in a presumably identical product with lower CBD content and produced in the same proximate time should also serve as a proxy for the presence of THC in this product line.

15. In her deposition, Dr. Orser stated that she is an advocate of retaining THC in formulated cannabis products such as Dixie X Dew Drop Tincture since she believes it is a key contributor to the effectiveness of the product.

16. There is no evidence to indicate that the 500 CBD Dixie Tincture consumed by Mr. Horn differed from the defendant's extraction, formulation or manufacturing processes used to produce the surrogate 500mg products evaluated by Dr. Orser and the 100mg product that plaintiff had tested.

17. EMSL provided a THC analysis to identify illicit drug. As indicated in their affidavit, EMSL used scientifically defensible test procedures, appropriate reference materials and calibrated instrumentation to produce an accurate and valid result.

18. As part of a state-sanctioned medical marijuana program, the state may require certification or the ability to meet defined standards for manufacturers and laboratories associated with that market. Different state marijuana programs could have different certification or statutory requirements. Although a non-state certified laboratory may not be able to participate in the medical marijuana program within that state, it does not preclude a laboratory from conducting analyses for cannabinoid substances using scientifically valid procedures.

19. Without any knowledge about the procedures, documentation and materials employed by EMSL Analytical, Inc., Dr. Orser makes the unfounded assertion that the test results produced by EMSL were inaccurate because the lab didn't maintain appropriate chain of custody documentation and failed to use proper reference materials for comparison with historical calibration curves. Dr. Orser's view is inconsistent with the information provided in the affidavit prepared by EMSL.

20. Dr. Orser provided no information regarding the procedures, documentation and materials employed by CannLabs for the analysis of the 500mg CBD surrogate products she included in her report and appears to hold EMSL to a different and more stringent standard than the one she applies to CannLabs.

21. A positive urine drug screen test result indicates exposure to a substance sufficient to exceed a defined minimum concentration threshold. The test result does not reflect a dose or amount administered or the time of administration other than being used within a certain interval.

KENNETH D. GRAHAM, Ph.D.

Subscribed and Sworn to before me this
22 day of October, 2020.

Notary Public

Commonwealth of Pennsylvania - Notary Seal
Katie A Parkinson, Notary Public
Montgomery County
My Commission Expires September 23, 2024
Commission Number 1379919